

FIG. 12 shows a bottom view of sensor 120, greatly enlarged, having body 170 formed from the hydrogel of the present invention. Light emitter 125 and receiver 135 are linearly aligned and are each connected to measurement unit 80 by their own lines (electric wires) 140. The function and operation of the sensor device is explained below.

The small dimensions of the sensor 120 and its ease of handling permit sensor 120 to be introduced through the vagina and attached to the presenting part of the fetus at a very early stage of labor. To do so, sensor 120 is pressed lightly at the center against the head of fetus 100, for example, by a moving forward a handle having a polygonal profile (not shown) on the distal end that fits into the polygonal profile 165 of cup 150.

Body 170 is pressed onto the fetal tissue by a forward motion of sensor 120. Since body 170 attaches without invading the fetal tissue, no impairment in the fetal tissue is caused. The forward force is transmitted directly by way of the polygonal profile and metal plate 155 to body 170.

When sensor 120 is pressed at the center against the fetal tissue, the peripheral zone 111 of cup 150 is the first to come in contact with the fetal tissue. The peripheral zone 111 then undergoes elastic deformation and the curvature of cup 150 is reduced. The hydrogel adhesive permits the peripheral zone 111 of cup 150 to yield in an elastic, spring-loaded manner when sensor 120 is pressed against the fetal tissue such that peripheral zone 111 rests on the fetal tissue with a slight initial tension. When body 170 has been pressed onto the fetal tissue, the slight initial tension caused by peripheral zone 111 of cup 150 on the fetal tissue causes the surfaces of light emitter 125 and receiver 135 to be in contact with the fetal tissue.

Attachment zone 110 is also pressed by body 170 against the fetal tissue. The pressing of sensor 120 against the fetal tissue thus takes place very gently but tightly at the center as well, but in any case this prevents any impairment of the fetal arterial blood flow in the area of peripheral zone 111.

As shown in FIG. 10, a tab-shaped ear 119 that projects radially outward beyond cup 150 and covers the fetal tissue in this area to prevent light from entering or being emitted can be attached in the area of emitter(s) 125 and/or receiver(s) 135. The light propagates radially beyond the area of cup 150 in an area of approximately 8 mm in the fetal tissue. Therefore, it is advantageous to cover this area with ears 119.

The attachment of sensor 120 to the fetal tissue using the conductive hydrogel of the present invention permits parts which are electrically insulated with respect to each other, namely metal plate 155 and body 170, to be used as electrodes, for example, as ECG electrodes.

The especially simple design of sensor 120 and its very small shape should be emphasized. Sensor 120 can be produced very easily and economically (as a disposable item). Nevertheless, sensor 120 fulfills the need for a non-invasive, reliable, and durable means of attachment to the fetal tissue and satisfactory reception of signals for the purpose of measuring vital parameters of a fetus during labor and delivery.

Although illustrated and described herein with reference to certain specific embodiments, the present invention is nevertheless not intended to be limited to the details shown. Rather, various modifications may be made in the details within the scope and range of equivalents of the claims and without departing from the spirit of the invention.

What is claimed:

1. In a process for producing a medical device attaching to a patient, the improvement comprising the steps of:

applying a coating of a precursor composition comprising acrylic acid monomer and an alcoholamine to said medical device; and

polymerizing said precursor composition to produce a hydrogel which is adhesive under both wet and dry conditions.

2. A process as recited in claim 1 wherein said alcoholamine is diisopropanolamine.

3. A process as recited in claim 2 wherein said device is a fetal pulse oximeter sensor attaching to a presenting part of a fetus and monitoring at least one fetal parameter during labor and delivery.

4. A process as recited in claim 2 wherein said precursor further comprises water, a photoinitiator, and a crosslinking agent.

5. A process as recited in claim 4 wherein said device is a fetal pulse oximeter sensor attaching to a presenting part of a fetus and monitoring at least one fetal parameter during labor and delivery.

6. A process as recited in claim 2 wherein said precursor comprises up to about 40% water, up to about 30% acrylic acid, 0.3–0.4% photoinitiator, 0.05–0.20% crosslinking agent, and up to about 30% diisopropanolamine.

7. A process as recited in claim 6 wherein said precursor comprises about 29% water, about 25% acrylic acid, about 0.35% 2-hydroxy-2-methyl-1-phenyl-propane-1-one, about 0.10% polyethylene glycol (400) diacrylate, and about 24% diisopropanolamine.

8. A process as recited in claim 6 wherein said precursor comprises about 39% water, about 29% acrylic acid, about 0.35% 2-hydroxy-2-methyl-1-phenyl-propane-1-one, about 0.10% polyethylene glycol diacrylate, and about 28% diisopropanolamine.

9. A process as recited in claim 6 wherein said precursor comprises about 35% water, about 18% acrylic acid, about 0.35% 2-hydroxy-2-methyl-1-phenyl-propane-1-one, about 0.10% polyethylene glycol (400) diacrylate, and about 30% diisopropanolamine.

10. A process as recited in claim 6 wherein said precursor comprises about 39% water, about 16% acrylic acid, about 0.35% 2-hydroxy-2-methyl-1-phenyl-propane-1-one, about 0.15% polyethylene glycol (400) diacrylate, about 28% diisopropanolamine, and about 13.0% vinyl pyrrolidone.

11. A process as recited in claim 6 wherein said precursor comprises about 25% water, about 19% acrylic acid, about 0.35% 2-hydroxy-2-methyl-1-phenyl-propane-1-one, about 0.10% polyethylene glycol (400) diacrylate, and about 8% diisopropanolamine.

12. A process as recited in claim 6 wherein said precursor comprises about 11% water, about 22% acrylic acid, about 0.33% 2-hydroxy-2-methyl-1-phenyl-propane-1-one, about 0.17% polyethylene glycol (400) diacrylate, and about 14% diisopropanolamine.

13. A process as recited in claim 6 wherein said precursor comprises about 38% water, about 16% acrylic acid, about 0.35% 2-hydroxy-2-methyl-1-phenyl-propane-1-one, about 0.15% polyethylene glycol (400) diacrylate, about 28% diisopropanolamine, and about 13% vinyl pyrrolidone.

14. A process as recited in claim 6 wherein said device is a fetal pulse oximeter sensor attaching to a presenting part of a fetus and monitoring at least one fetal parameter during labor and delivery.

15. A process as recited in claim 1 wherein said hydrogel is conductive.

16. A process as recited in claim 1 wherein said device is a non-invasive fetal probe attaching to a presenting part of a fetus and monitoring at least one fetal parameter during labor and delivery, said probe comprising:

a body having a surface adapted for securing the probe to the fetus to be monitored, said body comprised of said hydrogel which is adhesive under both wet and dry conditions;

a sensor carried by said body and detecting at least one fetal parameter; and